

# HITSP Manage Consumer Preference and Consents Capability

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HITSP/CAP143



Healthcare Information Technology Standards Panel

*Submitted to:*

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*Submitted by:*

**Capabilities Team**



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## 1.0 INTRODUCTION

This Healthcare Information Technology Standards Panel (HITSP) document is divided into Requirements Analysis, External Capability Options, Design Specifications and Standards sections which may be used by analysts, architects and implementers. Analysts refer to this document to determine if the Capability satisfies their requirements. Architects and system implementers refer to this document as the architectural specifications for a system design, while software developers will use a Capability as the source of the design for interoperable information exchange. The Appendix lists requirements satisfied by this Capability.

All sections may be useful to analysts and architects. However as shown in Table 1-1, different readers may find specific sections of greater interest and utility. This table is provided as an aid to readers to assist them in identifying sections to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 1-1 Reader's Guide for Capability**

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements Analysis	2.1 Introduction	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses, and identifies the system roles supported by the Capability
	2.2 Requirements	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions and exchange content. It shows how these roles can be assigned at a higher level to real world systems, such as an Electronic Health Record
Section 3.0 External Capability Options	3.1 Security and Privacy	Policy Analysts Architects Business Analysts Developers	Describes the integrated and optional security and privacy functions supported by the Capability
	3.2 Information Exchange Options	Architects Business Analysts Developers	Describes the external information exchange options associated with topology, or message and document content, as applicable
Section 4.0 Design Specification	4.1 Requirements Mapped to Constructs	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2 Constraints and Assumptions	Business Analysts Developers	Lists the context that is necessary to use the Capability, including constraints, assumptions, pre-conditions, post-conditions and triggers
	4.3 Specified Interfaces by System Role	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use
Section 5.0 Standards	5.1 Standards Used	Program Managers Policy Analysts Architects Business Analysts Developers	Lists regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2 Standards Gaps and Overlaps	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues



## 1.1 CAPABILITY OVERVIEW

This Capability addresses management of consumer preferences and consents as an acknowledgement of a privacy policy. This Capability is used to capture a patient or consumer agreement to one or more privacy policies; where examples of a privacy policy may represent a consent, dissent, authorization for data use, authorization for organizational access, or authorization for a specific clinical trial. This Capability also supports the recording of changes to previously agreed to privacy policies to reflect changes in consumer preferences, such as when a patient changes their level of participation or requests that data no-longer be made available because they have left the region.

The enforcement of the currently agreed to privacy policies is embedded in HITSP/SC108 Access Control as enforced by HITSP/TP20 Access Control. Therefore this Capability addresses only the management of the privacy policy acknowledgements.

The acknowledgement to the privacy policy is structured according to the HL7 CDA standard with recording the act of acknowledgement of one or more privacy policies. At this time, the consent directive document is basically an unstructured document with appropriate CDA metadata to identify it accordingly when shared by any of the defined document sharing topologies. As the standards develop, the content of the privacy policy is expected to be encoded within the same CDA document such that more powerful policies can be expressed.

Privacy policy (e.g., Consent) management has the following characteristics as documented in HITSP/TP30 Manage Consent Directives:

- Patient consent directives are captured electronically in a consent repository
- Patient consent is withdrawn and that withdrawal is captured in a repository
- Patient consent is revoked and that revocation is captured in a repository
- Patient consent directives are transmitted to a Requester
- Processing of patient consent directives is logged in audit trail

## 1.2 SCOPE

A Capability enables business and policy requirements for a business need to be implemented through information exchanges specified in HITSP constructs. The objective of a Capability is to provide the bridge between the business, policy and implementation disciplines by defining a set of information exchanges at a level relevant to policy and business decisions and specifying the use of HITSP constructs sufficiently for implementation. A Capability supports stakeholder requirements and business processes and includes information content, infrastructure, security and privacy. The design of Capabilities leverages existing HITSP constructs and communication methodologies. As new constructs become available, the scope of this Capability may be extended.

## 1.3 COPYRIGHT PERMISSIONS

### COPYRIGHT NOTICE

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## 1.4 REFERENCE DOCUMENTS

A list of key reference documents and background material is provided in the table below. These documents can be retrieved from [HITSP Web Site](#).

Table 1-2 Reference Documents

Reference Documents	Document Description
<a href="#">HITSP Acronyms List</a>	Lists and defines the acronyms used in this document



Reference Documents	Document Description
<a href="#">HITSP Glossary</a>	Provides definitions for relevant terms used by HITSP documents
<a href="#">TN900 – Security and Privacy</a>	TN900 is a reference document that provides the overall context for use of the HITSP Security and Privacy constructs
<a href="#">TN901 - Clinical Documents</a>	TN901 is a reference document that provides the overall context for use of the HITSP Care Management and Health Records constructs
<a href="#">TN903 – Data Architecture</a>	TN903 is a reference document that provides the overall context for use of the HITSP Data Architecture constructs
<a href="#">TN904 – Harmonization Framework and Exchange Architecture</a>	TN904 is a reference document that provides the overall context for use of the HITSP Harmonization Framework and Exchange Architecture constructs

## 1.5 GUIDANCE FOR USE OF A CAPABILITY

NOTE: For questions related to details on HITSP Capabilities and HITSP System Roles, please refer to HITSP/TN904 Harmonization Framework and Exchange Architecture Technical Note.

To use a HITSP Capability, a HITSP Interoperability Specification or an implementation conformance statement must assign specific systems to one or more HITSP Capability System Roles and identify how the HITSP Capability Options are to be addressed. In order to assign systems to HITSP System Roles, the reader uses Table 2-3 Supported Information Exchanges to determine what systems can support the specific information exchanges required. For an example of how HITSP System Roles and systems are mapped, readers can consult a HITSP Interoperability Specification Table 3-3 Orchestration of Capabilities by System. In the case of an Implementation Guide, systems can be assigned to HITSP System Roles using a similar methodology.

The use of a HITSP Capability implies that these specific rules will be followed:

- For each HITSP Capability System Role listed in Table 2-2 Capability System Roles, the defined responsibilities of that HITSP Capability System Role are supported. Responsibilities for the HITSP Capability System Role are defined as support for the HITSP Construct interfaces listed in Section 4.3 Specified Interfaces by System Role. Support implies that the system assigned to the HITSP Capability System Role makes the associated HITSP construct interfaces available for use by other systems. For those HITSP construct interfaces in Section 4.3 that have associated content optionality, the HITSP Capability System Role must comply with the optionality condition listed in Table 4-10 Implementation Conditions.
- Responsibilities also include the constraints and assumptions associated with use of a Capability, as outlined in Table 4-3 Context. For those Capabilities with Section 3.2 options, the following additional rules apply:
  1. Each topology option listed in Table 3-2 Topology Related Options should be supported by the implementation
  2. Each content import option listed in Table 3-3 Content Import Options should be supported by the implementation
  3. Each document content option listed in Table 3-4 Document Content Options should be supported by the implementation



## 2.0 REQUIREMENTS ANALYSIS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 2-1 Reader's Guide for Section 2.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 2.0 Requirements Analysis	2.1 Introduction	Policy Managers Policy Analysts Executive Leadership	Provides an overview of the requirements which this Capability addresses, and identifies the system roles supported by the Capability
	2.2 Requirements	Program Managers Policy Analysts Executive Leadership Architects Business Analysts	Defines the actual information exchanges supported by the Capability in terms of exchange actions and exchange content. It shows how these roles can be assigned at a higher level to real world systems, such as an Electronic Health Record

### 2.1 INTRODUCTION

Table 2-2 summarizes the system roles of the Capability. Section 2.2 identifies how these system roles participate in the set of information exchanges.

**Table 2-2 Capability System Roles**

System Role	System Role Definition
Document Sender	The system that sends the document
Document Receiver	The system that receives the document
Document Registry and Repository	The system which registers the document, maintains a repository of documents and responds to a query for documents
Consent Directive Responder	The system that responds to a query for consent directives
Consent Directive Requestor	The system that queries or submits a request for consent directives
Consent Directive Registry and Repository	The system which registers consent directives, maintains a repository of consent directives and responds to queries or requests for consent directives

### 2.2 REQUIREMENTS

#### 2.2.1 INFORMATION EXCHANGES

Table 2-3 defines each of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA) or Exchange Content (EC) used.

**Table 2-3 Supported Information Exchanges**

Information Exchange Identifier	Exchange Action	Exchange Content
A	Send & Receive	Unstructured Document
B	Request & Response	Consent Directives

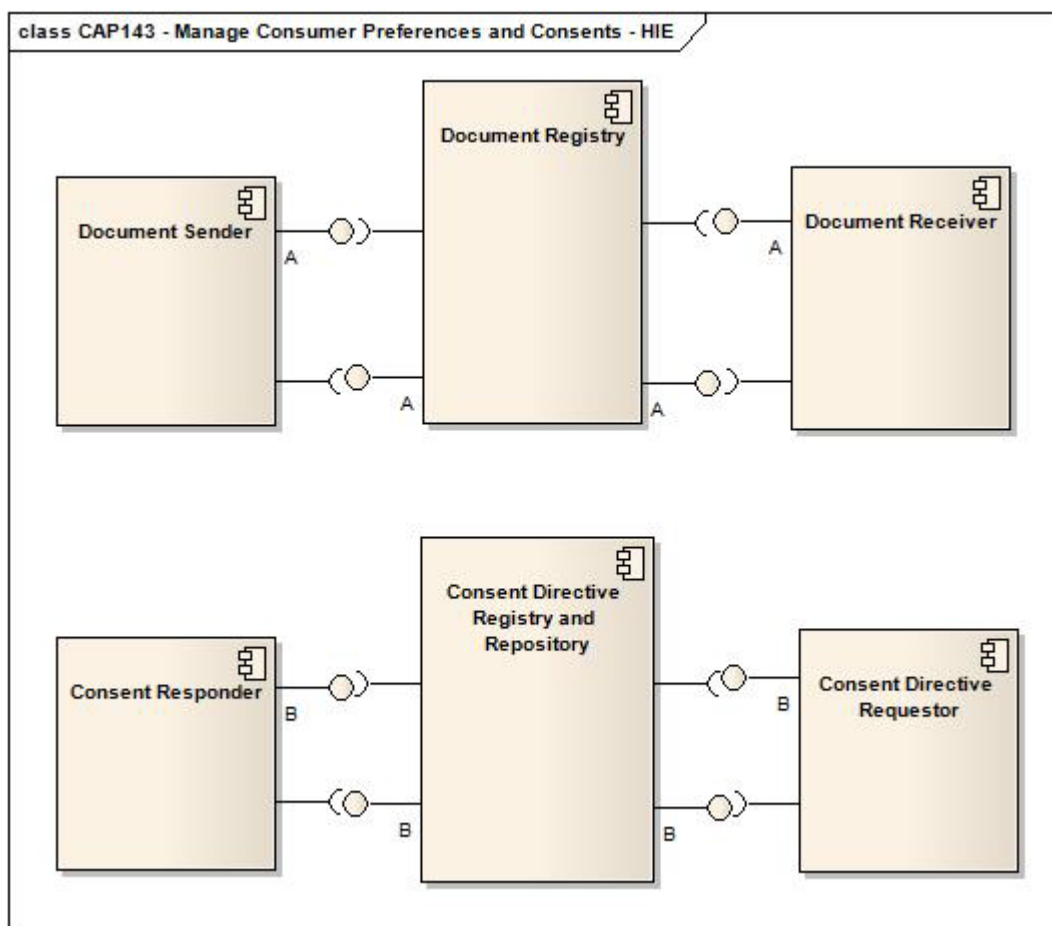
Figure 2-1 identifies how this Capability supports various system roles within multiple system architectures. For example, either an Electronic Health Record (EHR) system or a Health Information Exchange (HIE) might fill a document repository system role in an information exchange). In an implementation architecture, system roles may be combined locally (e.g., Hospital EHR System) and in





others, the system roles may be provided by multiple-distributed trusted third parties (e.g., pharmacies within an HIE).

**Figure 2-1 Information Exchanges Between System Roles**



## 3.0 EXTERNAL CAPABILITY OPTIONS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 3-1 Reader's Guide for Section 3.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 3.0 External Capability Options	3.1 Security and Privacy	Policy Analysts Architects Business Analysts Developers	Describes the integrated and optional Security and Privacy functions supported by the Capability
	3.2 Information Exchange Options	Architects Business Analysts Developers	Describes the external information exchange options associated with topology and message and document content as applicable

This section is primarily for architects, engineers and analysts. It allows those who consider using this Capability to evaluate and/or constrain the options that are externally made available for the Capability implementers.

Interoperability among system roles defined by this Capability often requires the selection of consistent options.

### 3.1 SECURITY AND PRIVACY

The application of Security and Privacy is highly influenced by the security and privacy policies. The HITSP Security and Privacy Technical Note (HITSP/TN900) provides a detailed discussion of the Security and Privacy constructs, including consideration and appropriate context for needed security and privacy related policy decisions. Security and Privacy constructs are integrated comprehensively into the Service Collaborations. The actual constructs used and the way in which the constructs are used is dependent on the policies and physical setting. Conformance claims are against the Security and Privacy constructs that are chosen to enforce the policies.

### 3.2 INFORMATION EXCHANGE OPTIONS

Three types of information exchange options are externally offered by this Capability:

- Topology Related Options
- Content Import Options
- Document Content Options

The HITSP Exchange Architecture adds topology to the HITSP Harmonization Framework. Topology is the arrangement or mapping of networked Systems, especially the physical (real) and logical (virtual) interconnections between Systems. A Health Information Exchange<sup>1</sup> (HIE) is a special network system that provides intermediary services, such as directories, registries or translations. HITSP supports the following topologies:

- Portable Media (non-connected)

<sup>1</sup> The terms "RHIO" and "Health Information Exchange" or "HIE" are often used interchangeably. An HIE is a more general instance of a RHIO (Regional Health Information Organization). Both are a grouping of organizations with a business stake in improving the quality, safety and efficiency of healthcare delivery. NHIEs are HIEs that support the building blocks of the Nationwide Health Information Network (NHIN) initiative proposed by the Office of the National Coordinator (ONC) for Health Information Technology (HIT). To build a nationwide network of interoperable healthcare records, the effort must first develop at the local and state levels. The concept of NHIN requires extensive collaboration by a diverse set of stake holders. The challenges are many to achieve success for an HIE or a RHIO.



- System to System (point-to-point)
- System to HIE
- HIE to HIE

The following matrix portrays which of the typical network topologies (see HITSP/TN904 for details on topologies) are addressed within the Capability. Within each cell, “Available” indicates that the topology is supported while “Not Available” indicates that the topology is not supported.

**Table 3-2 Topology Related Options**

Topology	Available or Not Available
Point-to-Point	Available
E-mail	Available
Portable Media	Available
Document Share/Community	Available

In addition to providing topology options, a Capability may provide Information Content Import Options (see Table 3-3 Content Import Options). Note that subsets of the data content can be sent as appropriate for the Capability; but the responding system must be able to address the entire data content corresponding to the Exchange Content supported. Content subsets should be specified in the document that uses this Capability – either an Interoperability Specification or an implementation design document.

**Table 3-3 Content Import Options**

Document Display	Document Import	Document Discrete Data Import
Integrated	Option	N/A

Two content import options are offered:

- **Document Import Option** impacts the import of Documents processed by a Content Consumer interface. It requires the Document Consumer to have the ability to import into the healthcare record one or more of the received documents as a whole and display it as requested
- **Discrete Data Import Option** impacts the import of the HL7 CDA Documents processed by a Content Consumer interface. It requires the Document Consumer to have the ability to import the discrete data from one or more of the data modules in a structured form into the healthcare record. Coded values shall be maintained

This Capability supports the HITSP/C83 Clinical Document Architecture (CDA) Modules document profiles listed in Table 3-4. Any use of this Capability by either an Initiating or a Responding System MUST support at least one of the HITSP CDA documents listed below.

**Table 3-4 Document Content Options**

Optionality	Supported Document Types
R	Unstructured Document (HITSP/C62)
R	Consent Directive (HITSP/TP30)

Optionality Legend: “R” for Required, “O” for Optional, or “C” for Conditional

Please note that at least one of the options shall be supported either by the Initiating System or the Responding System.



## 4.0 DESIGN SPECIFICATION

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 4-1 Reader's Guide for Section 4.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 4.0 Design Specification	4.1 Requirements Mapped to Constructs	Program Managers Architects Business Analysts Developers	Maps the information exchanges developed in requirements to the actual HITSP construct used by the Capability to support the exchange
	4.2 Constraints and Assumptions	Business Analysts Developers	Lists the context that is necessary to use the Capability, including constraints, assumptions, pre-conditions, post-conditions and triggers
	4.3 Specified Interfaces by System Role	Business Analysts Developers	Identifies the constructs and their interfaces assigned to each system role. It also lists the implementation conditions for use

### 4.1 REQUIREMENTS MAPPED TO CONSTRUCTS

#### 4.1.1 CONSTRUCTS

Table 4-2 defines the mapping of the Information Exchanges supported by this Capability in terms of the Exchange Action (EA), Exchange Content (EC) and any Constraints applied to the Information Exchange with specific initiating and/or responding system interfaces. This provides the traceability of constructs to the information exchanges identified in Section 2.0 above. Content modules and terminology components are not listed here because they are referenced by other constructs, but do not provide an interface. HITSP/TN903 discusses how content modules and terminology components are referenced by other constructs.

**Table 4-2 Information Exchanges Mapped to Constructs**

Information Exchange Identifier	Exchange Type	Construct Identifier	Description
A – Send and Receive Unstructured Document	Action	HITSP/SC112 - Healthcare Document Management	The HITSP Healthcare Document Management Service Collaboration provides the ability to share healthcare documents using a set of topologies, such as Media, e-Mail, Point-to-Point, Shared within a Health Information Exchange, and Shared within a larger community (made up of potentially diverse Health Information Exchanges)
A – Send and Receive Unstructured Document	Content	HITSP/C62 - Unstructured Document	The HITSP Unstructured Document Component provides for the capture and storage of patient identifiable, unstructured document content, such as text, PDF, and images rendered in PDF
B – Request and Response Consent Directives	Content	HITSP/TP30 - Manage Consent Directives	The HITSP Manage Consent Directives Transaction Package describes the messages needed to capture, manage, and communicate rights granted or withheld by a consumer to one or more identified entities in a defined role to access, collect, use or disclose individually identifiable health information (IIHI), and also supports the delegation of the patient's right to consent. The transactions described in this construct are intended to be carried out by HITSP/TP13 – Manage Sharing of Documents



## 4.2 CONSTRAINTS AND ASSUMPTIONS

Table 4-3 specifies the context that must be provided in order to use the Capability, identifying any assumptions, pre-conditions, post-conditions, and triggers relevant for use of the Capability.

**Table 4-3 Context**

Assumptions, Pre-conditions, Post-conditions, and Triggers	Type of Context
Legal and governance issues regarding data access authorizations, data ownership, and data use are in effect	Pre-condition

## 4.3 SPECIFIED INTERFACES BY SYSTEM ROLE

This section specifies the HITSP Capability interfaces in terms of the System Roles identified in Table 2-2 Capability's System Roles.

Table 4-4 below specifies interfaces for the Document Sender system role as defined in Table 2-2.

**Table 4-4 Document Sender System Role Mapped to HITSP Construct Interfaces**

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Send Documents Directly	Initiating	Healthcare Document Management (HITSP/SC112)	R
Send Document through e-mail	Initiating	Healthcare Document Management (HITSP/SC112)	R
Publish Document Through Media	Initiating	Healthcare Document Management (HITSP/SC112)	R
N/A	Initiating	Unstructured Document (HITSP/C62)	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-5 below specifies interfaces for the Document Receiver system role as defined in Table 2-2.

**Table 4-5 Document Receiver System Role Mapped to HITSP Construct Interfaces**

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Receive Documents Directly	Responding	Healthcare Document Management (HITSP/SC112)	R
Receive Documents through e-mail	Responding	Healthcare Document Management (HITSP/SC112)	R
Receive Documents Through Media	Responding	Healthcare Document Management (HITSP/SC112)	R
N/A	Responding	Unstructured Document (HITSP/C62)	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-6 below specifies interfaces for the Registry and Repository system role as defined in Table 2-2.

**Table 4-6 Registry and Repository System Role Mapped to HITSP Construct Interfaces**

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Send Documents Directly	Initiating	Healthcare Document Management (HITSP/SC112)	[CAP143-1]
Send Document through e-mail	Initiating	Healthcare Document Management (HITSP/SC112)	[CAP143-1]
Publish Document Through Media	Initiating	Healthcare Document Management (HITSP/SC112)	[CAP143-1]



Receive Documents Directly	Responding	Healthcare Document Management (HITSP/SC112)	[CAP143-1]
Receive Document through e-mail	Responding	Healthcare Document Management (HITSP/SC112)	[CAP143-1]
Receive Document Through Media	Responding	Healthcare Document Management (HITSP/SC112)	[CAP143-1]
N/A	Initiating	Unstructured Document (HITSP/C62)	[CAP143-1]
N/A	Responding	Unstructured Document (HITSP/C62)	[CAP143-1]

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-7 below specifies interfaces for the Consent Directive Responder system role as defined in Table 2-2.

**Table 4-7 Consent Directive Responder System Role Mapped to HITSP Construct Interfaces**

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Send Documents Directly	Initiating	Healthcare Document Management (HITSP/SC112)	R
Send Document through e-mail	Initiating	Healthcare Document Management (HITSP/SC112)	R
Publish Document Through Media	Initiating	Healthcare Document Management (HITSP/SC112)	R
N/A	Initiating	Unstructured Document (HITSP/C62)	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-8 below specifies interfaces for the Consent Directive Requestor system role as defined in Table 2-2.

**Table 4-8 Consent Directive Requestor System Role Mapped to HITSP Construct Interfaces**

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
Request Consent Directive Directly	Initiating	Manage Consent Directives (HITSP/TP30)	R
Respond to Consent Directive Directly	Responding	Manage Consent Directives (HITSP/TP30)	R
Request Consent Directive through e-mail	Initiating	Manage Consent Directives (HITSP/TP30)	R
Respond to Consent Directive through e-mail	Responding	Manage Consent Directives (HITSP/TP30)	R
Request Consent Directive through media	Initiating	Manage Consent Directives (HITSP/TP30)	R
Respond to Consent Directive through media	Responding	Manage Consent Directives (HITSP/TP30)	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-9 below specifies interfaces for the Consent Directive Registry and Repository system role as defined in Table 2-2.

**Table 4-9 Consent Directive Registry and Repository System Role Mapped to HITSP Construct Interfaces**

Construct Interface	Interface Type	T/TP/SC or Content	T/SC/Content Optionality
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Send Documents Directly	Initiating	Healthcare Document Management (HITSP/SC112)	R
Send Document through e-mail	Initiating	Healthcare Document Management (HITSP/SC112)	R
Publish Document Through Media	Initiating	Healthcare Document Management (HITSP/SC112)	R
Receive Documents Directly	Responding	Healthcare Document Management (HITSP/SC112)	R
Receive Document through e-mail	Responding	Healthcare Document Management (HITSP/SC112)	R
Receive Document Through Media	Responding	Healthcare Document Management (HITSP/SC112)	R
N/A	Initiating	Consent Document (HITSP/TP30)	R
N/A	Responding	Consent Document (HITSP/TP30)	R

Optionality Legend: "R" for Required, "O" for Optional, or "C" for Conditional

Table 4-10 specifies optionality conditions referenced in Table 4-4 through Table 4-9 above.

**Table 4-10 Implementation Conditions**

Condition ID	Condition Description
[CAP143-1]	This system role is required when HIE topology is chosen



## 5.0 STANDARDS

The following table is provided as an aid to readers to assist them in identifying the parts of this section to focus on. Readers are encouraged to review all sections of this document to further their understanding of HITSP's work.

**Table 5-1 Reader's Guide for Section 5.0**

Document Section	Section Number	Intended Audience	Information Contained
Section 5.0 Standards	5.1 Standards Used	Program Managers Policy Analysts Architects Business Analysts Developers	List regulatory guidance, selected standards and informative references used by the Capability and all its supporting constructs
	5.2 Standards Gaps and Overlaps	Program Managers Policy Analysts Architects Business Analysts Developers	Identifies gaps or overlaps in standards to implement the Capability including a plan to resolve issues

### 5.1 STANDARDS USED

#### 5.1.1 REGULATORY GUIDANCE

Table 5-2 lists any regulatory guidance that determines or constrains use of standards.

**Table 5-2 Regulatory Guidance**

Regulation	Description
No applicable regulatory guidance	

#### 5.1.2 SELECTED STANDARDS

Table 5-3 lists the standards selected as relevant to this Capability.

**Table 5-3 Selected Standards**

Standard	Description
Health Level Seven (HL7) Version 3.0 Privacy Consent related specifications RCMR_RM010001 - Data Consent	The Data Consent RMIM captures the data and associations needed to (1) record or report a consumer's consent or dissent to authorize the access, collection, use, or disclosure of personally identifiable information; (2) convey a provider's request or intent to override a patient's recorded consent or dissent; (3) convey a type of consent directive associated with a privacy policy; or (4) to record or report a consumer's consent directive, which is to be applied to future access, collection, use or disclosure of personally identifiable information. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 or later, Cross Enterprise Sharing of Scanned Documents (XDS-SD) Integration Profile	This Integration Profile defines how to store healthcare metadata in clinical documents, including patient identifiers, demographics, encounter, order or service information, represented within a structured HL7 CDA R2 header, with a PDF or plaintext formatted document containing clinical information within a nonXMLBody. For more information visit <a href="http://www.ihe.net">www.ihe.net</a> to retrieve Volume 1, and Volume 2 of the Framework





Standard	Description
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0, Section 10 Cross-Enterprise Document Sharing (XDS.a) <b>DEPRECATED</b>	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. Section 10, Cross-Enterprise Document Sharing facilitates the registration, distribution and access across health enterprises of patient electronic health records. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The current version of the ITI-TF, rev. 4.0 for Final Text, specifies the IHE transactions defined and implemented as of August 22, 2007. The latest version of the IHE Technical Framework is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 Volume 2 Supplement 2007 – 2008 Cross-Enterprise Document Sharing-B (XDS.b)	The Cross-Enterprise Document Sharing-B Profile (XDS.b) supplement provides a new implementation choice for the Cross-Enterprise Document Sharing (XDS) Integration Profile based on use of the Web Services and ebXML Reg/Rep standards that is consistent with current developments and best practices in the industry. For more information visit <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 - Registry Stored Query Transaction for XDS Profile Supplement [ITI-18]	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The Registry Stored Query Transaction Trial Implementation Supplement specifies an IHE transaction that provides optimization and implementation simplification. This supplement is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0 XCA Supplement	The IHE IT Infrastructure Technical Framework defines specific implementations of established standards to achieve integration goals that promote appropriate sharing of health information to support optimal patient care. IHE Integration Profiles offer a common language that healthcare professionals and vendors may use in communicating requirements for the integration of products. The trial implementation version of the XCA Supplement to the ITI-TF, rev. 4.0 Final Text, specifies the IHE transactions that support access between communities in a manner compatible with the XDS Integration profile. This supplement is available at <a href="http://www.ihe.net">www.ihe.net</a>
Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework (ITI-TF) Revision 5.0, Basic Patient Privacy Consents (BPPC) Profile	The Basic Patient Privacy Consents (BPPC) profile provides a mechanism to record the patient privacy consent(s), a method to mark documents published to XDS with the patient privacy consent that was used to authorize the publication, and a method for XDS Consumers to use to enforce the privacy consent appropriate to the use. This profile complements XDS by describing a mechanism whereby an XDS Affinity Domain can develop and implement multiple privacy policies, and describes how that mechanism can be integrated with the access control mechanisms supported by the XDS Interfaces (e.g., systems). There are two key parts of the profile: 1) It provides a document content specification for capturing a patient acknowledgement of a privacy consent policy or policies. 2) It describes the method by which XD* Interfaces can enforce the privacy policies determined by the document confidentialityCode related to the patient privacy consents. The latest version of specification is available at <a href="http://www.ihe.net">www.ihe.net</a>
International Organization for Standardization (ISO) PDF/A ISO 19005-1b. Document management - Electronic document file format for long-term preservation - Part 1: Use of PDF (PDF/A)	Specifies how to use the Portable Document Format (PDF) 1.4 for long-term preservation of electronic documents. It is applicable to documents containing combinations of character, raster and vector data. For more information visit <a href="http://www.iso.org">www.iso.org</a>

### 5.1.3 INFORMATIVE REFERENCE STANDARDS

Table 5-4 includes reference standards that inform the overall semantic interoperability.



**Table 5-4 Informative Reference Standards**

Standard	Description
Health Level Seven (HL7) HL7 Version 3 Standard: Clinical Document Architecture (CDA), Release 2	The HL7 Clinical Document Architecture is an XML-based document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA is one instantiation of HL7's Version 3.0 Reference Information Model (RIM) into a specific message format. Of particular focus for HITSP Interoperability Specifications are message formats for Laboratory Results and Continuity of Care (CCD) documents. Release 2.0 of the HL7 Clinical Document Architecture (CDA) is an extension to the original CDA document markup standard that specifies the structure and semantics of clinical documents for the purpose of exchange. CDA R2 includes a prose document in HTML, XML schemas, data dictionary, and sample CDA documents. CDA R2 further builds upon other HL7 standards beyond just the Version 3.0 Reference Information Model (RIM) and incorporates Version 3.0 Data Structures, Vocabulary, and the XML Implementation Technology Specifications for Data Types and Structures. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Internet Engineering Task Force (IETF) The application/pdf Media Type (RFC 3778)	PDF, the "Portable Document Format", is a general document representation language that has been in use for document exchange on the Internet since 1993. This document provides an overview of the PDF format, explains the mechanisms for digital signatures and encryption within PDF files, and updates the media type registration of "application/pdf". For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Internet Engineering Task Force (IETF) Tags for the Identification of Languages, "Request for Comment" (RFC) #3066, January, 2001	Describes a language tag for use in cases where it is desired to indicate the language used in an information object, how to register values for use in this language tag, and a construct for matching such language tags. For more information visit <a href="http://www.ietf.org">www.ietf.org</a>
Health Level Seven (HL7) Consent related vocabulary including Confidentiality Codes	HL7 concept domains, including ConfidentialityCodes, ActInformationCategoryCode, ActInformationAccessType, ActInformationAccessContextCode, AuthorizedParticipationFunctionCode, ActPolicyType, ActConsentType, and ActMaskableCode For more information visit <a href="http://www.hl7.org">www.hl7.org</a>
Health Level Seven (HL7) V3 RBAC, R1-2008, HL7 Version 3 Standard: Role Based Access Control (RBAC) Healthcare Permissions Catalog, Release 1, February 2008	The Healthcare Permission Catalog provides the necessary content for creating interoperable roles facilitating inter-organizational communications and information sharing among healthcare organizations and their business partners. For more information visit <a href="http://www.hl7.org">www.hl7.org</a>

## 5.2 STANDARDS GAPS AND OVERLAPS

Table 5-5 identifies the information exchange requirements and known standards gaps, along with the recommended resolutions to the gaps.

**Table 5-5 Information Exchange Requirements (IER) and Associated Standards Gaps**

IER Gap Description	Responsible HITSP TC	Design Approach	Required Standards Now Unavailable for Constructs	SDO Working on Unavailable Standards	Expected Availability
None					

Table 5-6 lists any standards overlaps and describes plans to resolve each of the overlaps.

**Table 5-6 Information Exchange Requirements (IER) and Associated Standards Overlaps**

IER Number	Summary Description	Standard Overlap	Recommended Resolution
None			



## 6.0 APPENDIX

This section may include additional materials referenced throughout this document, such as requirements analysis tables and figures. If the Capability is yet to be implemented, it may contain the candidate standards for Tier 2 evaluations.

The following legacy Interoperability Specifications were used to create this Capability:

- HITSP/IS01 – Electronic Health Records Laboratory Results Reporting
- HITSP/IS02 – Biosurveillance
- HITSP/IS03 – Consumer Empowerment and Access to Clinical Documents via Networks
- HITSP/IS04 – Emergency Responder Electronic Health Record
- HITSP/IS05 – Consumer Empowerment and Access to Clinical Documents via Media
- HITSP/IS07 – Medication Management
- HITSP/IS08 – Personalized Healthcare
- HITSP/IS09 – Consultations and Transfers of Care
- HITSP/IS10 – Immunization and Response Management
- HITSP/IS11 – Public Health Case Reporting
- HITSP/IS12 – Patient-Provider Secure Messaging
- HITSP/IS77 – Remote Monitoring



## 7.0 DOCUMENT UPDATES

The following sections provide the details of updates made to this document.

### 7.1 NOVEMBER 9, 2009

No changes. This is the first published version of the document.

### 7.2 JANUARY 18, 2010

- Update to reflect HITSP Capability Template Version 2.3
- Minor correction to Figure 2-1
- The document was updated in Section 1.1: “to reflect changes in consumer preferences” was added to the first paragraph for clarity
- Table 2-2 added the appropriate definitions for System Roles

### 7.3 JANUARY 25, 2010

Upon approval by the HITSP Panel on January 25, 2010, this document is now Released for Implementation.

